This repor. is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 34-R-0027
CUSTOMER NUMBER: 197

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Emergent Biodefense Operations Lansing Inc
Emergent Biodefense
3500 N. Martin Luther King Blvd
Lansing, MI 48909

Telephone: (517) -327-7232

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs	3000	4254	77	6325	10656
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
0. Sheep					
1. Pigs					
2. Other Farm Animals					
3. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIG (b)(6), (6)(7)(C)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print) (b)(6), (6)(7)(C)

DATE SIGNED 11/14/08

PH , which is obsolete.)

NOV 17 2008 NI

JUSTIFICATION OF ANIMALS IN COLUMN "E"
Emergent BioDefense Operations Lansing USDA year October 1, 2007 to September 30 2008
Registration # 34-R-0027

6325 guinea pigs were used in studies reported in Column E during this USDA reporting period.

1. Explanation of procedures involving pain or distress.

   A. Study 1 utilized 68 guinea pigs in column E in a protocol to assess the potency of an Investigational New Drug.
   B. Study 2 utilized 5145 guinea pigs in column E as part of a study requiring certain designated endpoints in order to adequately assess the performance of a test article. The study is conducted as part of a release protocol for an FDA licensed product.
   C. Study 3 utilized 181 guinea pigs in column E in a study designed to assess the proficiency of individuals in performing the test in Study #2, allowing them to conduct testing on release lots of a product intended for human use.
   D. Study 4 utilized 60 guinea pigs in column E in a study to assess the efficacy of a therapeutic product to counter the lethal effects of an infectious agent.
   E. Study 5 utilized 211 guinea pigs in a study to assess an alternate delivery system of the product release tested in Study #2.
   F. Study 6 utilized 94 guinea pigs in column E in a study to assess the impact of producing the product in Study #2 in a different area.
   G. Study 7 utilized 4 guinea pigs in a study to assess the immunogenicity of a biologic product.
   H. Study 8 utilized 240 guinea pigs in a study designed to assess the ability of an alternate test system to detect out of range potency of lots of product.
   I. Study 9 utilized 322 guinea pigs in a study required to qualify a bank of challenge organism required to test an FDA licensed product.

2. Scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress would interfere with results.
   A. Gulnea pigs reported in column E in study 1 could not receive treatment for pain or distress, as morbidity/mortality are recorded, and figure into the final analysis of the test. Appropriate treatments would alter the accuracy of observations made on the test animals. However, animals observed to be moribund or symptomatic are removed from the test to reduce pain and distress.
   B. Guinea pigs reported in column E in studies 2,3,4,5,6,and 8 could not receive treatment for pain or distress without altering the results of a test specifically designed to assess the potency of a product for human use. Appropriate treatment would consist of medications that would alter the natural disease process of the challenge organism, therefore nullifying the purpose of the test. Anything altering the designated endpoints of the test would directly alter the calculations performed to analyze test date, the results of which must fall within

pre-determined limits. Literature searches for alternative were performed and presented to the IACUC as part of protocol review. The use of animals in Study 8 is further justified as they were used as part of developmental work to craft a potential alternate test method that would not utilize any animals in column E in the future.

C. Guinea pigs reported in column E in study 7 were used in a study to determine the immunogenicity of a product intended fur future use in humans. The testing involved challenge with a virulent organism. Treatment of the animals would involve the use of drugs or medications all of which alter the natural course of the disease process, therefore altering test results.

D. Guinea pigs reported in column E in Study 9 could not be given pain relieving medication or other treatment, as the natural course of infection of the challenge is required to qualify it for challenge studies required in release testing of an FDA licensed product.